

K083340

Attachment 3 – 510(k) Summary

NOV 26 2008

510(k) Summary for Levitronix CentriMag Primary Console

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the Safe Medical Devices Act (SMDA) of 1990 and Title 21 of the Code of Federal Regulations, Part 807, and in particular §807.92.

A. Application Information:

Date Prepared: November 11, 2008

Submitter's Name & Address: Levitronix LLC
45 First Avenue
Waltham, MA 02451

Contact Person: Susan K. Hamann
Regulatory Affairs Manager
Ph: (781) 466-6553
Fax: (781) 622-5090
e-mail: shamann@levitronix.com

B. Device Information:

Trade or Proprietary Name: Levitronix CentriMag® Primary Console

Common or Usual Name: Cardiopulmonary Bypass Pump Console

Classification Name: Class II, DWA, 21 CFR – 870.4380
Control, Pump Speed, Cardiopulmonary Bypass

Performance Standard: Performance standards do not currently exist for these devices. None established under section 514 of the Food, Drug and Cosmetic Act.

C. Predicate Device:

Levitronix CentriMag Console Software Version 2.02 – 510(k) (K081221)

D. Device Description

The CentriMag Primary Console is a microprocessor-based device. The microprocessor generates the primary Motor control signal, monitors system sensors, generates front display outputs, and provides alarm functions. The microprocessor acquires the sensor data for use in generating operator displays and alarms. An alphanumeric screen is used to display monitored data, system options, and menus. Operator adjustable alarms and parameters are accessible via the system menus.

E. Intended Use

The Levitronix CentriMag Primary Console is indicated for use with the Levitronix CentriMag Extracorporeal Blood Pumping System. The Levitronix CentriMag Extracorporeal Blood Pumping System is indicated to pump blood through the extracorporeal bypass circuit for extracorporeal circulatory support for periods appropriate to cardiopulmonary bypass (up to six hours). It is also indicated for use in extracorporeal circulatory support systems (for periods up to six hours) not requiring complete cardiopulmonary bypass (e.g., valvuloplasty, circulatory support during mitral valve reoperation, surgery of the vena cava or aorta, liver transplants etc).

F. Technological Characteristics

The Levitronix CentriMag Primary Console has technological characteristics similar to the predicate device.

The Levitronix CentriMag Primary Console is a microprocessor-based device. The microprocessor generates the primary Motor control signal, monitors system sensors, generates front display outputs, and provides alarm functions. The microprocessor acquires the sensor data for use in generating operator displays and alarms. An alphanumeric screen is used to display monitored data.

The CentriMag Primary Console uses single phase AC power and is capable of a flow rate of up to 9.9 LPM. Each Primary Console contains a rechargeable internal battery that is capable of maintaining Primary Console functionality in the event of a loss of AC Power.

G. Comparison to Predicate Device

The Levitronix CentriMag Primary Console has indications for use which is substantially equivalent to the predicate device, is composed of the same or equivalent materials as the predicate device, has equivalent design features as the predicate device, and has functional characteristics which are the same or equivalent to those of the predicate device. Due to the

equivalency of indications for use, materials of composition, design features, and functional characteristics, the device raises no new safety or effectiveness issues.

H. Summary of Performance Data

The performance characteristics of the Levitronix CentriMag Primary Console were tested and compared with Levitronix performance specifications established for the device and with the commercially available predicate device.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 26 2008

Levitronix LLC
c/o Susan Hamann
Regulatory Affairs Manager
45 First Avenue
Waltham, MA 02451

Re: K083340
Levitronix CentriMag Primary Console
Regulation Number: 21 CFR 870.4380
Regulation Name: Cardiopulmonary Bypass Pump Speed Control
Regulatory Class: Class II
Product Code: DWA
Dated: November 11, 2008
Received: November 12, 2008

Dear Ms. Hamann:

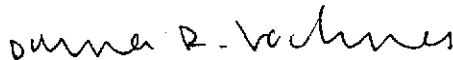
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.


If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



 Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Attachment 1 – Indications for Use Statement

Applicant: **Levitronix LLC**

510(k) Number (if known): K083340

Device Name: **CentriMag® Primary Console (with V3.00 Application Software)**

Indications for Use:

The Levitronix CentriMag Primary Console is indicated for use with the Levitronix CentriMag Extracorporeal Blood Pumping System. The Levitronix CentriMag Extracorporeal Blood Pumping System is indicated to pump blood through the extracorporeal bypass circuit for extracorporeal circulatory support for periods appropriate to cardiopulmonary bypass (up to six hours). It is also indicated for use in extracorporeal circulatory support systems (for periods up to six hours) not requiring complete cardiopulmonary bypass (e.g., valvuloplasty, circulatory support during mitral valve reoperation, surgery of the vena cava or aorta, liver transplants etc).

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Vachner
(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K083340

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